Realist evaluation of cancer rehabilitation services in South Wales (REEACaRS): a mixed methods study protocol

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ABSTRACT

Introduction Long-term and late effects of cancer treatments can cause functional limitations and reduce quality of life. Cancer rehabilitation services, which can comprise physical exercise, psychological support and educational interventions depending on the individual’s needs, have been found to have a positive effect on health-related quality of life worldwide. However, accessibility or the lack of awareness on available help can act as barriers and influence the uptake of services, resulting in people having unmet rehabilitation needs. In Wales, UK, 41% of people, who have had health and social care needs resulting from cancer and its treatments, reported that they did not receive care when needed. The reason for this lack of support has not yet been fully investigated. The aim of this study is to investigate the conditions in which cancer rehabilitation services work and their underpinning mechanisms in South Wales, UK, specifically addressing barriers, facilitators and costs.

Methods and analysis Realist evaluation, which explains for whom a service works in what circumstances and how through context-mechanism-outcome pattern conjunctions, will be used in three phases to investigate the conditions in which cancer rehabilitation services work and their underpinning mechanisms. Phase 1 will be secondary analysis of a cancer rehabilitation database from a local Health Board to gain context to who are accessing rehabilitation. Phase 2 will be thematic analysis of face-to-face, semistructured rehabilitation participant interviews and healthcare professional interviews with health-care providers worldwide. Two case studies and cost-consequences analysis of cancer rehabilitation provide information on the service models and how much they cost in South Wales and can inform policy makers on what works and potential areas for improvement to meet people’s needs.

Strengths and limitations of this study

● Mixed methods within realist evaluation enable in-depth exploration of cancer rehabilitation services, the conditions that make services work and their underpinning mechanisms.
● Secondary analysis of an existing rehabilitation database sheds light on the characteristics of people using the services and some outcomes, such as change in fatigue levels and quality of life.
● Face-to-face semistructured interviews with healthcare professionals and people affected by cancer provide rich insight into the value, barriers and facilitators of services and allow exploration of the mechanisms that make rehabilitation work.
● Two case studies and cost-consequences analysis of cancer rehabilitation provide information on service models and how much they cost in South Wales and can inform policy makers on what works and potential areas for improvement to meet people’s needs.
● Potential limitations of this study include the use of an existing rehabilitation database maintained by healthcare professionals and the lack of time to conduct long-term follow-up which might influence generalisability of findings.

BACKGROUND OF STUDY

The growing number of cancer diagnoses is a concern of healthcare providers worldwide. In the UK, 2.5 million people were living with cancer in 2015. This number is expected to reach 2.9 million in the UK by 2020.1 With advanced screening and treatment opportunities, more people are living with and beyond cancer. However, long-term and late effects of cancer treatments can cause both physical and psychological health problems which can affect people’s quality of life, social functioning, family and work roles and financial situations.2 The most common health issues people face after cancer treatment are fatigue, mobility problems, breathlessness, malnutrition, anxiety and depression.2

In 2013, it was estimated that at least 500,000 people in the UK were experiencing health problems and disability after cancer treatment...
which required long-term help and support from health services.3

Cancer rehabilitation can provide help with both physical and psychological health problems. It has been defined by the National Institute for Health and Care Excellence (NICE) as a complex intervention which helps people attain maximal functioning, independence and adaptation to changes caused by cancer.4 Cancer rehabilitation is wide-ranging aiming to address the various needs of people affected by cancer. It has been implemented worldwide in many different formats, including: physical (exercise classes, dietary advice), psychological (mindfulness intervention, cognitive behavioural therapy) and multidimensional rehabilitation programmes (physical and psychosocial elements combined), either as individual therapy or group session.5 These rehabilitation programmes have been found to have a beneficial effect on people’s functional and clinical outcomes (lung volume, muscle strength, body mass index) and health-related quality of life.5,6

In Wales (UK), cancer rehabilitation services are provided by National Health Service (NHS) Wales with support from local and national charities. Service provision is based on NICE and Welsh Government guidelines.4 8 9 The cancer rehabilitation pathway developed by one of the biggest cancer charities is divided into four main stages depending on when rehabilitation is needed: diagnosis and care planning, treatment, post-treatment and palliative and end-of life care.10 Following NICE recommendations, cancer rehabilitation is usually provided by a multidisciplinary team of dieticians, nurse specialists, occupational therapists, physiotherapists, psychologists and speech and language therapists in collaboration with oncologists and other physicians.1

Both physical and psychological health problems are addressed by these professionals depending on people’s needs. Physical exercise classes, patient education, nutritional advice, swallowing assessment, counselling and vocational rehabilitation are some of the many services provided for people affected by cancer. However, it is estimated that 30% of the UK cancer population still have unmet rehabilitation needs.2 The Wales Cancer Patient Experience Survey identified that 41% of the people who needed support after treatment in Wales did not have access to health and social care, including physiotherapy.11 12 The reason for this lack of support has not yet been fully explored.

Barriers to cancer rehabilitation, which can lead to unmet needs, have been identified in the literature internationally. Systemic barriers were described by Canadian breast cancer survivors as lack of awareness of existing services, availability of services, cost and duration of travel.13 In the UK, delayed referral and misinformation have been identified as barriers among people with central nervous system tumours.14 People’s perceptions of rehabilitation can also act as a barrier. Canadian breast cancer survivors did not wish to attend sessions as they thought rehabilitation was a reminder of cancer.13 However, people with central nervous system tumours, who had experience with physiotherapy as cancer rehabilitation, described it as a way to get back to normal.14 It has also been recognised that rehabilitation is more accepted in other areas of healthcare, such as neurology and musculoskeletal problems.15 Clearly, people’s understanding of rehabilitation can influence the uptake of services. Therefore, it is vital to investigate how services are perceived and what other barriers patients face.

Healthcare professionals also face barriers when providing cancer rehabilitation. In the UK, lack of time, knowledge and confidence have been reported to cause difficulties for healthcare providers working with people affected by head and neck cancer.16 However, barriers to cancer rehabilitation have not been fully investigated in other cancer sites in the UK, and specifically in Wales. To provide seamless care and meet people’s needs, it is crucial to know how cancer rehabilitation services work. Particular attention needs to be given to how cancer rehabilitation is perceived and valued, individuals’ needs, both met and unmet, and the barriers people face in accessing services. In relation to service provision, it is important to understand the mechanisms which make rehabilitation work and the challenges healthcare professionals encounter when providing care.

METHODS
Aims and objectives

The aim of this study is to investigate the conditions in which cancer rehabilitation services work in South Wales, UK, and underpinning mechanisms. Specifically, it seeks to address the following objectives:

1. To identify the met and unmet needs of people who have been attending cancer rehabilitation services in South Wales.
2. To examine the ways in which two specialist cancer rehabilitation services have been providing help to meet people’s rehabilitation needs in South Wales.
3. To explore how the term cancer rehabilitation is perceived by:
   a. people who have received care from the services in South Wales.
   b. healthcare professionals working in the services in South Wales.
4. To identify the barriers and facilitators to people accessing and using cancer rehabilitation services in South Wales.
5. To investigate what people affected by cancer and healthcare professionals value in cancer rehabilitation.
6. To explore the resource use, associated costs and consequences of two specialist cancer rehabilitation services in South Wales.

Setting

Cancer rehabilitation services (n=2) located in the two Cancer Centres of South Wales, UK, will be investigated. The inclusion of these two services enables the
investigation of ways in which rehabilitation is provided in both urban and rural areas of South Wales. Moreover, the exploration of two service models has the potential to represent the wide-ranging nature of cancer rehabilitation.

One of the study sites is situated in a University Health Board’s Cancer Centre in South West Wales. Here, the service provides inpatient and outpatient specialist occupational therapy, physiotherapy and rehabilitation services. Person-centred, individualised care is informed by findings from an adapted version of the Holistic Needs Assessment (HNA).17 The rehabilitation programme may include one-to-one sessions or group Tai-Chi, hydrotherapy and circuit classes depending on people’s individual needs and goals. People affected by cancer can access the services directly through self-referral or can be referred by healthcare professionals at any point during the cancer rehabilitation pathway: diagnosis, treatment, post-treatment or end-of-life. The service has links to community and leisure activity providers, to assist people in accessing support closer to their home.

The second study site is based in a University NHS Trust, which is the cancer centre of South East Wales. Specialist inpatient and outpatient dietetics, speech and language therapy occupational therapy and physiotherapy services are provided. There is close collaboration between the different disciplines to ensure a holistic approach. Health assessment of people affected by cancer is conducted on first contact to provide goal-focused care which meets individuals’ needs. Although it is not based on formal HNA, the service aims to support people to stay as independent as possible from diagnosis until the end of life. Referral to rehabilitation is via medical staff or other healthcare professionals. However, some outpatient services such as pilates class and the dietetics drop-in clinic offer self-referral.

Research design

Realist evaluation developed by Pawson and Tilley is the chosen study design because it enables the investigation of how a programme works for whom and in what circumstances.18 In contrast with experimental designs, which are mostly interested in the effectiveness of an intervention, realist evaluation also looks at the conditions in which an intervention works. The unit of analysis in realist evaluation, which drives the evaluation process, is context-mechanism-outcome pattern (CMO) conjunction.19 Context refers to any influence that can support or inhibit a mechanism, including social and policy environment or participants’ family background.18 Mechanisms, which can be further divided into resources and reasoning, define how the intervention brings change into the target population’s life.19 Resources are the elements of the intervention that participants react to, while reasoning is the people’s thinking or response triggered by these resources. Mechanisms can work differently in various contexts resulting in both expected and unexpected outcomes.

Realist evaluation is theory-driven, which means that initial programme theories based on available information of how a programme works are tested and refined with data collection and analysis.18 Initial programme theories are developed through literature review, document analysis and engagement with service providers or experts, and provisional CMO conjunctions are made before data collection commences.20 In this study, validation of initial programme theories is supported by a steering group of local experts on cancer rehabilitation who also help with the identification of key literature.21 To thoroughly test programme theories, a wide range of research methods can be used in realist evaluation. Quantitative, qualitative and mixed methods are commonly adopted to support, dismiss or expand the initial programme theories.20 It is also possible that during data collection, new CMO conjunctions surface.22 The choice of research method in realist evaluation depends on the programme and its initial theories.20 Quantitative methods can be used to explore context and test outcomes, while qualitative methods can provide insight into the mechanisms of programmes and can help in the identification of unexpected outcomes and contexts.20 Pawson and Tilley also recommend that multiple data sources and research methods should be used as needed and if opportunity arises.23 In this study, once the initial programme theories are finalised, data collection occurs in three phases. The full realist evaluation process of this study is summarised in figure 1.

Phase 1

Phase 1 will be the secondary analysis of the South West Wales cancer rehabilitation service’s database. Secondary analysis is the investigation of existing data collected for other purposes such as patient registry.24 This method has been chosen, because the analysis of existing, real world data has been found to provide useful information on service impact, underuse, capacity of the workforce and on patient population, which can provide information on the context of cancer rehabilitation in Wales.25 Moreover, it is a time-efficient and economical way to make use of existing data.24

Participants and data source

Data from one-to-one assessments conducted on first contact with the South West Wales rehabilitation service and during a 12-week follow-up session have been collected in a database since 2014. The database contains information on gender, cancer site, date of diagnosis, patient discharge and pre-rehabilitation and post-rehabilitation assessment results. The team uses valid and reliable outcome measures, including: Timed Up and Go a functional walking test (TUAG),26 EuroQol Five Dimensions Questionnaire Five Level (EQ5D-5L), a generic quality of life measure27 and Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F), a measure of fatigue.28 This information is gathered to monitor change in rehabilitation participants’ functional status, to provide
person-centred care adjusted to individual needs and to investigate the impact of the services including goal achievement. Anonymised records of every person over the age of 18 years who attended cancer rehabilitation in the service between 2014 and 2017 will be analysed.

Analysis
The eight-step guidance developed by Cheng and Phillips will be used to lead secondary analysis. This approach includes the thorough understanding of the strength and weakness of the data and guides the development of a statistical analysis plan. In this study, descriptive statistics will be applied to describe the population attending the service, the normality of the data and the amount of missing pre-rehabilitation and post-rehabilitation data. With careful consideration to missing data, after the thorough examination of the database, a full statistical analysis plan will be developed.

Phase 2
Phase 2 will comprise qualitative semistructured interviews with healthcare professionals and people who have completed cancer rehabilitation provided by two cancer rehabilitation services in South Wales. Qualitative, in-depth exploration of the services seeks to address the following objectives: how the term cancer rehabilitation is perceived; what are the barriers and facilitators of care; what people value in cancer rehabilitation. Phase 2 can expand the knowledge gained from Phase 1 quantitative analysis and provide information on the mechanisms of how cancer rehabilitation works in South Wales.

Participants and data sources
Healthcare professionals and people affected by cancer will be recruited from both study sites to explore their experiences and perceptions of rehabilitation and how it works. The aim is to recruit up to 20 healthcare professionals and 20 rehabilitation participants. The sample size of 20 is advisable in qualitative research to provide credibility to the data. Analysis will be done concurrently with data collection to determine when data from the latest interviews starts repeating what participants said in previous interviews. If data repetition is achieved, recruitment of new participants and data collection can stop, which method is known as saturation. Purposive sampling will be used to achieve an accurate representation of cancer rehabilitation in South Wales by recruiting from a wide range of professionals with different backgrounds (dietetics, occupational therapy, physiotherapy, etc.).
speech and language therapy) and people with a wide range of cancer diagnoses. Inclusion and exclusion criteria are presented in Table 1.

Healthcare professionals and people affected by cancer will be recruited in two separate ways. Professionals, who are interested in being interviewed, will be identified by the study’s gatekeepers, who are cancer rehabilitation leads and managers at both services. People affected by cancer will be approached by their healthcare professionals and will be given a choice in which part of the study they would like to take part in: Phase 2, Phase 3 or both. Participants will be recruited for a 9-month period to allow at least three turnovers of rehabilitation participants, whose rehabilitation episodes can last for 12 weeks. Multiple turnovers can help in extending recruitment to a wide range of participants with different diagnoses.

Semistructured face-to-face interviews have been chosen as the data collection method, as they make use of a loose interview guide. This guide will enable the researcher to keep focused on the research objectives, while leaving space for interviewees to talk about other relevant topics. Face-to-face interviews will be used in preference to group discussion, because cancer can be a difficult topic to talk about and rehabilitation participants might not want to speak about their experiences in front of other people. However, participants may invite a companion to accompany them to the interview, if they do not wish to be alone. Having a companion can be advantageous, because it can provide further depth to the interviews and they can comfort the interviewees if they become distressed. Interviews will be audio recorded and transcribed verbatim.

Analysis
Thematic analysis will be used to identify meaningful themes and patterns in the transcripts. Thematic analysis is theoretically flexible, which means it does not belong to any theoretical framework. However, it is generally considered realist, which makes it suitable for this study. During the analysis, the six phase thematic analysis guideline developed by Braun and Clark will be used. To ensure the credibility of the findings, a second reviewer will analyse a sample of the transcripts. Methodological triangulation will also be applied, through the comparison of the qualitative interview findings to the patients’ rehabilitation records. To provide rigour, a reflective diary will be written by the principal investigator to explore her own role as a researcher and its effect on the study.

Phase 3
Phase 3 will comprise two case studies, namely the South West and South East cancer rehabilitation services, and cost-consequences analysis (CCA) of the study sites to explore the service models and their resource use. Case study design was chosen because it is a comprehensive investigation of a programme as it occurs in the real world without any manipulation with research intent. It examines the services in context, which makes it suitable to use in realist evaluation. This phase can provide information on both the mechanisms of how cancer rehabilitation works and the context which it works in. It seeks to address the following objectives: what met and unmet needs participants have; in what ways cancer rehabilitation services provide help to meet people’s needs.

To investigate the costs and resources used in rehabilitation and its outcomes, CCA will be conducted. CCA presents direct healthcare, non-healthcare and indirect costs and the outcomes of services in a disaggregated manner on a balance sheet which can be interpreted by policy makers. CCA has been found valuable in rehabilitation, where analysis needs to capture the complexity of the intervention, outcomes and related costs. CCA comprises two case studies, namely the South West and South East cancer rehabilitation services, and cost-consequences analysis (CCA) of the study sites to explore the service models and their resource use. Case study design was chosen because it is a comprehensive investigation of a programme as it occurs in the real world without any manipulation with research intent. It examines the services in context, which makes it suitable to use in realist evaluation. This phase can provide information on both the mechanisms of how cancer rehabilitation works and the context which it works in. It seeks to address the following objectives: what met and unmet needs participants have; in what ways cancer rehabilitation services provide help to meet people’s needs.

Participants and data sources
To explore the two cases, managers will be contacted to identify important documents (audit files, staff numbers, referral pathways) used in the organisation of the two cancer rehabilitation services. As part of the CCA, people affected by cancer will be recruited to fill Resource Use Measure (RUM) questionnaires which aim to capture costs of cancer and rehabilitation from the rehabilitation participants’ perspective. The RUM will be given to

<table>
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<tr>
<th>Table 1</th>
<th>Inclusion and exclusion criteria</th>
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<td>Healthcare professionals (Phase 2)</td>
<td>People affected by cancer (Phase 2 and Phase 3)</td>
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<tr>
<td>► Over the age of 18 years</td>
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<td>► Holding appropriate professional qualification and registration</td>
<td>► Students</td>
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<tr>
<td>► Over the age of 18 years</td>
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<tr>
<td>► Have been taking part in cancer rehabilitation provided by the two study sites</td>
<td>► Students</td>
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<tr>
<td>► Have the capacity to consent and participate</td>
<td>► Lack of training or professional registration</td>
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<tr>
<td>► Understand and able to communicate in English</td>
<td>► Less than 1 year experience in working with people affected by cancer</td>
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Every potential participant must be willing to take part.

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participants at two time points: at the beginning of their rehabilitation and after their 12-week follow-up assessment. The two questionnaires will be used to compare resource use before and after rehabilitation. All eligible participants will be included who are willing to take part in Phase 3 during the 9 months data collection period.

Analysis
The documents acquired from the service managers as part of the case studies will be used to describe the two service models and how rehabilitation is provided (staff levels, interventions provided, how many patients are seen).

For the CGA, a multisectoral costing perspective has been chosen to represent costs for NHS Wales, local cancer charities and people affected by cancer. This will include direct healthcare (hospital and primary care visits), non-healthcare (participant’s travel, equipment and medication expenses) and indirect costs (participants or their carers time off work related to cancer). Resource use will be determined based on information provided by the services and the adapted version of the UK Cancer Costs RUM.40 Where possible, published unit costs, such as Unit Costs of Health and Social Care,41 will be used to value resource use in sterling in the latest price available. With items where unit costs are not available, local finance records will be used.

In this study, costs are compared against outcomes, the consequences of the intervention, which will be determined by seeking permission from rehabilitation participants for access to their hospital notes containing clinical and patient reported outcomes (EQ5D-5L,27 FACT-F,28 TUAG,26 HNA17) routinely collected by the services. Costs and outcomes of the two cancer rehabilitation services will be listed on a balance sheet, providing easy interpretation of the findings and describing the two service models.

Patient and public involvement
A patient involvement facilitator and a local cancer charity representative are active members of the Steering group of this project and have helped in the design and development of this study.

Ethics and dissemination
This project has been reviewed by London South-East Research Ethics Committee and it has received a favourable opinion (17/LO/2123).

In the design of this project, the UK policy framework for health and social care research was followed.42 The main issues considered were confidentiality, anonymity, privacy, choice and information provided for participants. Detailed letters of invitation and information sheets will be provided for everyone who is interested in taking part, including any participant companions. Participants will be free to withdraw at any time during the study without an explanation. Written informed consent will be sought from every participant and any companions. All data collected during the conduct of this project will be anonymised.

This study is part of a PhD evaluating cancer rehabilitation services in South Wales. It is anticipated that the findings of the different phases will be written up for publication in academic journals and will be presented at conferences, both locally and internationally. The dissemination of the findings is especially important in Wales, where policy makers are trying to transform healthcare services to achieve the ‘Quadruple Aim’ of: population health improvement through prevention; enhancement in the quality of care; skills development and reformed work environment for the well-being and engagement of the healthcare workforce; and increased value for healthcare funding through the use of best practice.43 It is expected that this study will contribute to the knowledge base about cancer rehabilitation and will provide information to help get closer to the ‘Quadruple Aim’ through a comprehensive evaluation of the process, context and outcomes of delivering care and support within South Wales.

Strength and limitations
The findings of the realist evaluation process described above can be useful for policy makers and in programme implementation as it can provide information on the circumstances cancer rehabilitation services work, how it works and for whom and what outcomes can be expected.18 Conducting a CCA further enhances the impact of this study. It has been found to capture similar costs and outcomes as cost-utility analysis, which is commonly used in Health Technology Assessments, although it is presented in a format that is easy to interpret for managers and policy makers.44 CCA might also have the potential to oversee short-term impact of healthcare interventions.44

However, considering the complex nature of this study, limitations can arise and must be acknowledged. Accessing existing real-world data can pose some disadvantages. Post-rehabilitation data can be missing due to patients’ disengagement, health deterioration or death. In this study, depending on the mechanism of missingness, different statistical techniques will be used to make up for data loss. These techniques will be chosen based on their scientific value to provide unbiased results, and this can enhance the rigour of the study.29 Another disadvantage of using a real-world database is that the analysis of EQ5D-5L questionnaire has to be excluded, because the rehabilitation team misreported the results and, instead of calculating a utility score, they added up the different dimensions. However, EQ5D-5L data will be gathered prospectively by the principal investigator in Phase 3, which can provide information on utility score change during rehabilitation. In the prospective data collection of Resource Use Measures due to the time limits of this project, a third follow-up collection of costs and quality of life outcomes is not possible. Therefore, the long-term effect of cancer rehabilitation on direct healthcare.
and non-healthcare costs cannot be determined by this project.

CONCLUSION
This project aims to investigate the conditions in which cancer rehabilitation services work in South Wales and the mechanisms behind them by using realist evaluation. The secondary analysis of a clinical database, case studies of service models and costing of services can draw a complex picture on the context and outcomes, while qualitative interviews with people affected by cancer and healthcare professionals can give information about what mechanisms act behind the success or failure of cancer rehabilitation. New knowledge on people’s met and unmet rehabilitation needs, barriers, facilitators, value and cost of care are expected findings of this study, which can inform local healthcare providers on how to organise or improve services so that cancer rehabilitation can be used to its full potential. It can also provide information on common problems cancer rehabilitation services in South Wales share with other health services worldwide.

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Contributors
This study was proposed by JKC, TW and DF. JKC drafted the study protocol with the supervision of TW, DF and MJ. TW and DF provided significant help with the editing, WMW, JH, LLG and AT are members of the Steering group and have made important contribution to the design of the study, data collection and the editing of the study protocol. All authors read and approved the final version of this article.

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Competing interests
This study will be carried out as part of JKC’s PhD candidature and will contribute to the doctoral thesis.

Patient consent for publication
Not required.

Provenance and peer review
Not commissioned; externally peer reviewed.

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